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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,635	10/17/2003	Germaine Zocchi	F1584	1961

7590 04/20/2007

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EXAMINER	
FUBARA, BLESSING M	
ART UNIT	PAPER NUMBER
1618	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/688,635	ZOCCHI, GERMAINE	
	Examiner	Art Unit	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4 and 5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4 and 5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of request for reconsideration and remarks filed 8/21/06. Claims 4 and 5 are pending.

Rejections that are not reiterated herein are withdrawn.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 4 and 5 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Ellis et al. (US 6,277,365) or Tetsuhisa et al. (JP 2000-109892, Computer translation).

Ellis discloses composition comprising 0.00001 to about 5 wt% of antimicrobial agent (column 6, lines 36-38), which is polyhexamethylene biguanide hydrochloride; the composition also contains 0.015% xanthan gum; 0.015% GLUCQUAT 100 glycoside as surfactant in Example 1. Hyaluronic acid is disclosed in Example 3. However, in Test Solution 2, Ellis uses 15 ppm polyhexamethylene biguanide, 0.01% surfactant, and 0.3% xanthan gum. See also abstract; column 2, lines 40-45 and 54-67, columns 5 and 6 and claims 1-26. The 15 ppm is less than that required in the claims. The amount of the surfactant and the anionic biopolymer (hyaluronic acid or xanthan gum) meet the limitation of the amounts in the claims. Thus the difference between the claims and the prior art is in the amount of the biguanide antimicrobial agent. The composition contains water. Antimicrobial cleaning is a future intended use of the

composition and a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In this case, the claimed invention is a composition and the prior art discloses compositions.

In the instant case, both the composition of the prior art and the composition of the claimed invention have the same ingredients and would therefore have the same antimicrobial properties from the biguanide and the surfactant. The comprising language of the claims is open. Generally, differences in amounts of the antimicrobial agent will not support the patentability of the subject matter encompassed by the prior art unless there is evidence indicating such amount provides unexpected results or unusual results. "W[here] the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). And there is no demonstration in applicant's specification showing that the recited amount of the biguanide provides unexpected and unusual results.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the formulation according to Ellis. One having ordinary skill in the art would have been motivated to use the appropriate amount of the antimicrobial agent, which in combination with the surfactant and the anionic biopolymer would produce a composition that have the desired antimicrobial properties.

Tetsuhisa discloses a composition that comprises 0.001-10 wt% chondroitin sulfate and/or hyaluronic and polyhexamethylene biguanide or salt thereof (abstract). The concentration of the biguanide or ammonium chloride derivative is 0.00001-0.1% (claims 1-5)

and specifically discloses that the preferred concentration of the biguanide is from 0.00001-0.001% (see detailed description section at page 3, which concentration duffers from the claimed concentration. The composition also contains surfactants (claim 6) and the amount of the surfactant is from 0.1-5%, and preferably 0.01-10% (page 3 of detailed description section), and this meets the limitation of the claimed amount. The composition contains water.

Thus, Tetsuhisa teaches the claimed composition and the difference between the claims and the prior art is in the amount of the biguanide antimicrobial agent. Antimicrobial cleaning is a future intended use of the composition and a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In this case, the claimed invention is a composition and the prior art discloses compositions.

In the instant case, both the composition of the prior art and the composition of the claimed invention have the same ingredients and would therefore have the same antimicrobial properties from the biguanide and the surfactant. Generally, differences in amounts of the antimicrobial agent will not support the patentability of the subject matter encompassed by the prior art unless there is evidence indicating such amount provides unexpected results or unusual results. "W[here] the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). And there is no demonstration in applicant's specification showing that the recited amount of the biguanide provides unexpected and unusual results.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the formulation according to Tetsuhisa. One having ordinary skill in the art would have been motivated to use the appropriate amount of the antimicrobial agent, which in combination with the surfactant and the anionic biopolymer would produce a composition that have the desired antimicrobial properties.

Response to Arguments

3. Applicant's arguments filed 8/21/06 have been fully considered but they are not persuasive.

Applicants argues:

a) Ellis and Tetsuhisa are both directed to ophthalmic arts in which the compositions are used for "treating contact lenses or the surface of an eye."

b) It would not be obvious to use PHMB at 15 ppm in the case of Ellis when the claimed invention calls for 0.01% to 5% because there will be no motivation to increase the amount of the PHMB from 15 ppm to 0.01% to 5%.

c) It would also not be obvious to use a PHMB of 0.00001 to 0.001% (0.1 ppm to 10 ppm) in the case of Tetsuhisa when the claim calls for 0.01% to 5% because one of ordinary skill in the art would not be motivated to increase the amount of the PHMB to arrive at the claimed amounts.

Response:

Regarding a), it is noted that the claims are directed to composition that is clearly defined in the body of the claims, the preamble describes the intended use of the composition. Since the composition of the prior art has the same components as the claimed composition, the composition of the prior art is capable of performing the intended use. Both the claimed

composition and the prior art composition contain the same antimicrobial agent, PHMB, which is capable of antimicrobial activity. Antimicrobial cleaning is an intended use of the composition and a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In this case, the claimed invention is a composition and the prior art discloses compositions.

Regarding b), it is noted that while Ellis uses 15 ppm in the examples, Ellis teaches that the antimicrobial agent is present at 0.00001 to 5% (column 6, lines 36-38), with the 5% touching the claimed upper limit of the antimicrobial agent. It thus flows reasonably from the teaching of Ellis that any amount of antimicrobial agent within 0.00001 to 5% may be used as desired.

Regarding c), it is noted that while Tetsuhisa prefers to use 0.00001-0.001% biguanide, Tetsuhisa also teaches that an amount of 0.00001-0.1% biguanide can be used as discussed in the rejection. Amounts within the range of 0.00001-0.1% touches points within the claimed range of 0.01% to 0.1%, and specifically the upper limit of Tetsuhisa is the same as the upper limit of the claimed range.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference

claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 4 and 5 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 6,479,044. Although the conflicting claims are not identical, they are not patentably distinct from each other because issued claim 1 comprises anionic surfactant, polyhexamethylene biguanide, non-anionic surfactant, fragrance and water, and the instant claim 1 contains anionic surfactant, water and polyhexamethylene biguanide. While issued claim 1 is not identical with instant claim 1, instant claims 4 and 5 taken as a whole represent obvious variation of the issued claims 1 and 2.

6. Claims 4 and 5 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 3 of copending Application No. 10/224,692. Although the conflicting claims are not identical, they are not patentably-distinct from each other because anionic biopolymer of examined claim 4 includes anionic surfactant species of the copending application and the polyhexamethylene biguanide is the same in both the examined and copending claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's Request:

Applicant recognizes the rejection under the obviousness type double patenting and requests that the rejection be held in abeyance.

Response:

The rejection will not be held in abeyance. According to MPEP 804 1B states "the "provisional" double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that "provisional" double patenting rejection is the only rejection remaining in one of the applications. If the "provisional" double patenting rejection in one application is the only rejection remaining in that application, the examiner should then withdraw that rejection and permit the application to issue as a patent, thereby converting the "provisional" double patenting rejection in the other application(s) into a double patenting rejection at the time the one application issues as a patent.

If the "provisional" double patenting rejections in both applications are the only rejections remaining in those applications, the examiner should then withdraw that rejection in one of the applications (e.g., the application with the earlier filing date) and permit the application to issue as a patent. The examiner should maintain the double patenting rejection in the other application as a "provisional" double patenting rejection, which will be converted into a double patenting rejection when the one application issues as a patent."

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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SUPERVISORY PATENT EXAMINER